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K042919

8.0 Premarket Notification 510(k) Summary

[As required by section 807.92(c)]

Applicant:	Michael J. Morris R2 Diagnostics, Inc. 412 South Lafayette Blvd. South Bend, IN 46601 USA
Contact:	Dr. Peggy S. Carter R2 Diagnostics, Inc. 412 South Lafayette Blvd. South Bend, IN 46601 TEL: (574) 288-4377 FAX: (574) 288-2272
Date:	October 8, 2004
Trade Name:	R2 Diagnostics FibroTek FIB
Common Name:	Fibrinogen test
Classification Name:	Test, Fibrinogen (per 21 CFR section 864.7340)
Comparison Device:	Fibrinogen Assay Set, K800826

Description of the Device and Intended Use

FibroTek FIB fibrinogen kit contains Human Thrombin 200, Fibrinogen Calibrator Plasma, and Imidazole Buffered Saline (IBS) and is intended for use in the quantitative determination of fibrinogen in citrated human plasma. The fibrinogen test is a quantitative assay used in the general patient population and for patients identified as having possible fibrinogen disorders. The fibrinogen test should be used in a clinical laboratory by qualified laboratory professionals.

Summary of Substantial Equivalence Comparisons

R2 Diagnostics FibroTek FIB is substantially equivalent in intended use and performance to Fibrinogen Assay Set. Both the predicate device and the proposed product are formulated to determine fibrinogen levels in plasma. In correlation studies normal and abnormal patient plasma, as well as plasma samples from patients undergoing heparin therapy, were tested using both reagents. Comparison of data from fibrinogen testing at two sites and on two different instrument types yielded correlation coefficients of r^2 = 0.969 (photo-optical), slope = 0.859 and r^2 = 0.958 (mechanical), slope = .848. Within-run and between-run precision studies were also performed and CV's of less than 8% were obtained for the proposed device. CV's of less than 6% are reported for the predicate device in the manufacturers Instructions for Use.

Conclusion: Substantial Equivalence Statement

In Summary, the identical intended use, similar technological characteristics and the performance data provided in this premarket notification demonstrate that R2 FibroTek FIB is substantially equivalent to (Fisher Diagnostics) Pacific Hemostasis Fibrinogen Assay Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 29 2004

Peggy Carter, PhD
Director, Product Development
R2 Diagnostics
412 S. Lafayette Blvd.
South Bend, IN 46601

Re: k042919
Trade/Device Name: FibroTek FIB
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation product assay
Regulatory Class: Class II
Product Code: GIS, KQJ
Dated: November 17, 2004
Received: November 19, 2004

Dear Dr. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

6.0 Indications for Use

510(k) Number (if known): K042919

Device Name: FibroTek FIB

Indications for Use:

Statement of Indications for Use

The FibroTek FIB fibrinogen kit contains a lyophilized thrombin reagent, lyophilized calibrator plasma, and Imidazole Buffered Saline (IBS) for use in the quantitative determination of fibrinogen in citrated plasma. The fibrinogen test is a one-stage quantitative test performed on diluted plasma samples in the general patient population. The fibrinogen test is used to detect disorders of fibrinogen. The FibroTek FIB Fibrinogen Assay Kit should only be used in an appropriate clinical laboratory by qualified laboratory professionals.

Prescription Use X		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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(Posted November 13, 2003)